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In re Application of	:
Gordon L. Letts et al	:
Serial No.: 09/516,194	: PETITION DECISION
Filed: March 1, 2000	:
Attorney Docket No.: 102258.285	:

This is in response to the petition under 37 CFR 1.144, filed April 11, 2005, requesting withdrawal of an improper restriction requirement.

BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 111 on October 5, 2001, and contained claims 1-115. In a first Office action, mailed May 8, 2001, a first examiner set forth a restriction requirement, as follows:

Group I – claims 1-9, drawn to compounds; and
Group II – claims 10-115, drawn to compositions.

In addition, applicants were required to elect a species from whichever group was elected.

Applicants replied on June 8, 2001, electing Group II, with traverse, and the species identified by Example 11 on page 52 of the specification.

The examiner mailed a new Office action to applicants on July 24, 2001, in which, claims 1, 9, 18, 32, 41-103 and 107-115 were withdrawn from consideration as reading on non-elected inventions. Claim 1 was rejected under 35 U.S.C. 112, second paragraph as indefinite. Claims 2-8, 10-17, 19-31, 33-40 and 104-106 were objected to as being directed to misjoinder of inventions, but would be allowable if limited to the elected invention defined by the examiner.

Applicants replied on October 24, 2001, amending claims 1-8, 10-17, 19-31, 33-40 and 104-106 and canceling all other claims. The restriction requirement continued to be revised and all other rejections addressed.

The examiner mailed a Final Office action to applicants on January 22, 2002, responding to the traversal by stating that the claims would be examined to the extent they read on the elected invention, withdrawing claim 1 as drawn to a non-elected invention and objecting to all other claims as directed to a misjoinder of nitro and nitroso compounds. Applicants filed a reply and a Notice of Appeal on July 22, 2002.

Applicants filed a petition from the examiner's restriction on April 18, 2002. A decision granting the petition and returning the application to the examiner for further action on all of the claims was rendered on October 18, 2002. The examiner mailed an Advisory Action on January 20, 2003, denying entry of the amendment of July 22, 2002.

In response to a Notice withdrawing the finality of the Office action of January 22, 2002, mailed February 21, 2003, applicants submitted a new amendment of the claims on February 25, 2003. The amendment was deemed to not be in proper form by letter mailed August 29, 2003, and applicants provided a corrected amendment on September 5, 2003. The examiner mailed a non-Final Office action to applicants on November 25, 2003, rejecting claim 2 under 35 U.S.C. 102(b) as anticipated by Morozowich. Claims 2, 4-8, 14-17 and 107 were rejected under 35 U.S.C. 103(a) as unpatentable over Bezuglov or Del Soldato in view of Garvey (437 or 863) or Bandarage. Claim 107 was rejected under 35 U.S.C. 112, first paragraph as lacking enablement.

Applicants replied on February 24, 2004, by amending claims 2, 3 and 107 and responding to the rejections of record.

Due to retirement of the first examiner a new examiner was assigned the application for further prosecution. The new examiner in an Office action mailed August 16, 2004, set forth a 44 way restriction requirement which is not repeated herein and required an election of species from which ever group was elected.

Applicants replied with a vigorous traverse of the requirement, electing Group II and the same species as before. Applicants suggested that the claims could properly be divided into only four groups, as follows:

Groups I-XI – claims 1-2 and 116, drawn to compounds of formula I;
Groups XII-XXII – claims 4, 10-13, 19-27 and 33-36, drawn to compositions utilizing the compounds of Formula I;
Groups XXIII-XXXIII – claims 5-8, 14-17, 28-31 and 37-40, drawn to methods of use of the compounds of Formula I; and
Groups XXIV-XLIV – claims 104-106, drawn to a kit comprising the compounds of Formula I.

Applicants noted that all of these claims were examined by the previous examiner following the previous petition decision and should all continued to be examined now.

The examiner mailed a non-Final Office action to applicants on January 13, 2005, maintaining the restriction requirement due to undue burden on the Office, but indicating that process claims of the same scope as allowed product claims would be rejoined and fully examined upon

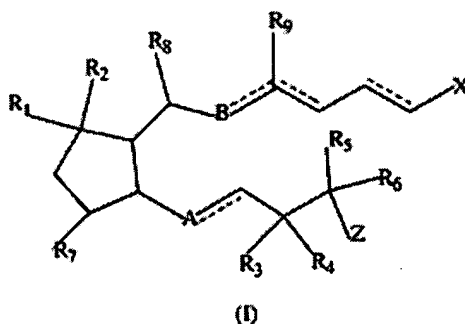
allowance of a product claim. Claim 116 was rejected under 35 U.S.C. 112, first paragraph, as lacking enablement. Claims 2-3 were rejected under 35 U.S.C. 112, second paragraph, as indefinite. Claim 2 was rejected under 35 U.S.C. 103(a) as unpatentable over Del Soldato. The elected species was indicated as allowable.

Applicants replied on April 11, 2005, by amending the specification in several places, amending claims 2 and 23 and adding claim 117. The rejections were addressed appropriately and the restriction requirement again traversed by filing of the instant petition. (It is noted that the amendment was found to be non-compliant and applicants so notified and a compliant amendment was filed on May 4, 2005.

DISCUSSION

The initial restriction requirement was traversed by applicants. The examiner proceeded with examination of the claims based on an election of species. The first petition was directed to the examiner's action in examining only a portion of the claims related to the elected species rather than following the guidelines of M.P.E.P. 803.02. The petition was granted on the claims remaining in the application, significantly less than the number originally filed. Following the petition decision the first examiner mailed a new non-Final action on the merits of the claims with the claims now being rejected over art. Applicants' reply was then considered by a second examiner who made a new restriction requirement. It is this requirement that is the subject of this petition.

The new examiner based the requirement for restriction on formula I:



Formula I represents a basic prostaglandin structure with the variables being defined in Claim 2. The structure further requires the presence of a nitro or nitroso group.

An analysis of the claims pending shows that they may be divided into four general categories, compounds, compositions based on the compounds, methods of treatment using the compositions and kits containing the compounds. Within the compounds encompassed by formula I (claims 2, 3 and 116) the examiner found 10 separate patentably distinct compounds based on the differences in variables R_1 and R_2 taken together or separately, Z and X. An eleventh group was also set forth which encompassed any compounds not covered by the first ten groups. This rationale was applied to the compositions (claims 4, 10-13, 19-27 and 33-36), methods of treating using the compositions (claims 5-8, 14-17, 28-31 and 37-40) and kit claims (claims 104-106), respectively, resulting in a 44 way restriction requirement.

Restriction under 35 U.S.C. 121 is a tool available for an examiner to use when examining complicated applications which may contain more than one claimed invention. Restriction is generally made between different categories of invention, but may also be made within the same category of invention. Here, the examiner has made restriction between compounds, compositions, methods of use and kits. Compounds and compositions are generally considered to be the same class of invention. Frequently patentability of a composition is dependent on the compound from which it is made. If the compound is novel it stands to reason that any composition made using that compound is also novel. Thus upon determination of patentability of the compound claims, the composition claims would also be rejoined and allowed. Similar rationale is applied to kit claims where the inventive novelty lies with the compound from which it is made. Further, upon determination of allowability of compound or composition claims, method of use claims containing all of the limitation of the compound/composition claims would be rejoined and fully examined for patentability under the guidelines of *In re Ochiai*. Thus restriction into four general categories of invention is here not improper, however it remains likely that all claims will eventually be rejoined should the compound claims be found allowable.

With respect to the dividing of Formula I into eleven (or more) groups based on the variables attached to the base group, it is noted that the first examiner made no such division, but did require an election of species in order to determine where to begin examination. Having been given a species from which to start examination the examiner found the species, itself, allowable over the prior art discovered. The examination was then expanded to a limited number of additional species which were also found allowable. The examiner attempted to limit allowance of the application to these examined species and equivalents. This was improper and the examiner was reversed in a petition decision. Upon further searching the examiner discovered prior art which rendered some species unpatentable and then rejected the claims accordingly. As the first examiner had considered the Markush group of claimed compounds in their entirety the second examiner in order to be consistent and give full faith and credit to the first examiner's work should have done the same. The purpose of a Markush group is to allow claiming of a large number of closely related (i.e. not patentably distinct) compounds to be examined together. The criteria for forming a Markush group is that the compounds encompassed thereby have a significant common core structure and an activity which is directly related thereto. The Markush group provided by Formula I above appears to satisfy that criteria in that the core structure is anchored by a five member ring having specific alkyl moieties attached thereto. Of the moieties directly attached to the ring, for R_1 , R_2 , and R_7 , only a limited number of very common possibilities exist (i.e. H, OH, Cl, ONO or ONO_2 or R_1 and R_2 together are $=CH_2$ or $=O$). The same applies to the two longer alkyl chains attached to the ring where most of the variables are simple and common alternatives (H or a bond, lower alkyl, etc.). Only X and Z have more significant and distinct possibilities. However, it has not been shown that they provide the activity of the compounds. Therefore, in view of the first examiner's action in setting forth an election of species within the entire Markush group, the second examiner should have continued the same election of species requirement, especially in view of the prior art applied in the last Office action done by the previous examiner.

In view of the above, the restriction requirement between compounds (Groups I-XI), compositions (Groups XII-XXII), methods of treating (Groups XXIII-XXXIII) and kits (Groups

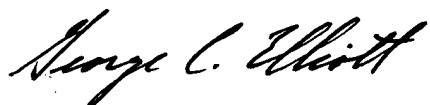
XXXIV-XLIV), as suggested by applicants, is maintained as proper. Within each group an election of species is found to be proper and is maintained and the examiner directed to follow the guidelines of M.P.E.P. 803.02. Should the elected species (a compound) be found allowable, consideration of rejoinder of composition, method and kit claims must be considered.

DECISION

The petition is **GRANTED** to the extent indicated above.

The application will be forwarded to the examiner for further consideration of the amendment filed April 11, 2005, not inconsistent with this decision.

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0519 or by facsimile sent to the general Office facsimile number, 571-273-8300.



George C. Elliott
Director, Technology Center 1600